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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,560	12/20/2005	Itzhak Bentwich	050992.0300.13USPC	9481

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,560	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007 and 10 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-18-2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on June 18, 2007 and July 20, 2007.

Currently, claims 21-49 are pending.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Election/Restrictions

Applicant's election with traverse of 21-28, 32-42, and 47-49 in the reply filed on July 20, 2007 is acknowledged. The traversal is on the ground(s) that the present application was filed under 35 U.S.C. 371 and therefore the restriction requirement under 35 U.S.C. 121 was misapplied. This is found persuasive and therefore, all pending claims will be examined in the instant case.

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

New Objections/Rejections Necessitated by Amendments

In the instant case, applicant has cancelled all previously examined claims and added new claims, claims 21-49. Therefore, the following objections/rejections are necessitated by claim amendments filed on June 18, 2007.

Claim Objections

Claims 36-49 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 21-35, respectively. The only "apparent" difference between the respective claims is the structure of the "first" and "second" viral nucleic acids. Irrespective of the recitation of "first" or "second" viral nucleic acid, it is found that the nucleic acid consisting of 50 to 131 nucleotides forms a hairpin and the nucleic acid consisting of 17 to 24 nucleotides bind to a binding site of an mRNA in the two sets of substantial duplicate claims, thereby rendering claim 36-49 identical to claims 21-35. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and /or chemical properties, functional characteristics, structure/function correlation, or any combination thereof.

In the instant case, the breadth of claims 21-49 embraces both disclosed and yet to be discovered genera of viral nucleic acids that have a structure of miRNA precursor. The size of viral genome is so enormous that different subtypes and strains of various viruses were continuously being identified even shortly prior to the filing date of the instant application.

Consider for example the number of HBV strains reported in Table 1 or Figure 2 of Arauz-Ruiz et al. reference (*Journal of General Virology,* 2002, 83:2059-2073), which further teaches that there is genetic variability of HBV by different serological types (or subtypes) of the HBV surface antigen.

Similar to the myriad variable HBV sequences, HIV-1 genome sequence was known for its broad variability of subtypes of HIV-1 genome sequences. See McGrath et al. (*Virus Research,* 2001, 76:137-160), who teach that HIV-1 or any retrovirus evolves through recombination and mutation, thereby generating diverse genomic sequences.

Given the divergence and diversity of viral genes/strains/subtypes as taught by Arauz-Ruiz et al. and McGrath et al., the breadth of claimed genus "viral nucleic acid" and subgenera "DNA virus", "RNA virus", and "retrovirus" embrace countless identified and unidentified nucleic acids derived from any viral genome that exists in a biological world. Moreover, even the specifically recited viruses (e.g., human adenovirus of DNA virus, Barmah forest virus of RNA virus, HIV-1 virus of retrovirus) comprise genetically variable subtypes, which increase in number through recombination and mutation depending on their host organism.

As broadly claimed, the specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented every species of the claimed genera of viruses. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991), which clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (see page 1117).

Corollary to the instant claims to broad genera of viruses in the instant application, in *Fiddes,* claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class since the specification provided only the bovine sequence (See *Fiddes v. Baird,* 30 USPQ2nd 1481 at 1483).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

As discussed above, the skilled artisan cannot envision the detailed structure of the encompassed genus of isolated viral nucleic acids, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Claims 21-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are newly entered claims which recite "17 to 24 nucleotides" and "50 to 131 nucleotides" for viral nucleic acids. Although the specification as originally filed contains support for "18 to 24 nucleotides" and "50 to 120 nucleotides", it does not have adequate support for the specific length parameter of "17 to 24 nucleotides" and "50 to 131 nucleotides". Further, the specification as originally filed lack any specific support for the claimed stem segments of 19 to 71 nucleotides and loop segments of 3 to 19 nucleotides. Further, there is no support for the claimed "72.7%" or "44.1%" complementarity. With regard to the claimed length limitations, applicant argues that specific SEQ ID NOs satisfy the length limitations. See pages 10-13 of applicant's remarks filed on June 18, 2007. Although the SEQ ID NOs exemplified by applicant may satisfy the structural limitations set forth in the claims, none of them satisfies the claimed broad length "parameter"; that is, no individual SEQ ID NO pointed out by applicant meets the "17 to 24 nucleotides", "50 to 131 nucleotides", stem segments of "19 to 71 nucleotides" and

loop segments of "3 to 19 nucleotides" with "72.7%" complementarity in its entirety. Further, the claimed value of "-11.3 Kcal/mol" for a negative free energy is not specified or described in the specification. Applicant argues that the mere statement that "Matthews et al." reference is incorporated in the specification satisfies the claimed value of "-11.3 Kcal/mol". Nowhere in the "Matthews et al." reference is there a teaching that pinpoints the exact and precise value of "-11.3 Kcal/mol". Further, the myriad of viruses claimed in the instant case are not adequately described in the specification. It is noted that the applicant states in the specification that the Tables are submitted in computer readable form (see page 2); however, no electronic medium containing such Tables has been filed with this application. Therefore, it is Office's position that no proper determination whether the specification as originally filed satisfies the written description requirement for the claimed viruses cannot be made in the instant case. Regardless of the presence or absence of Tables containing the claimed viruses, claims reciting names of viruses are considered to introduce new matter by virtue of claim dependency (e.g., claim 28 depends from claim 21 that contains new matter).

Accordingly, the passages pointed out by applicant in support of the claimed invention are not sufficient to satisfy the written description requirement and therefore introduce new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

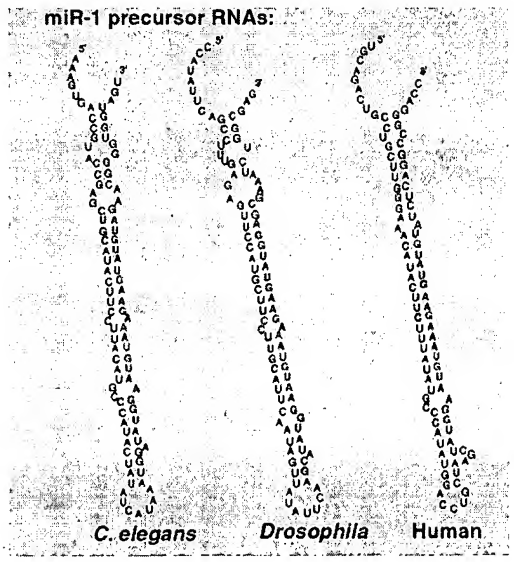
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

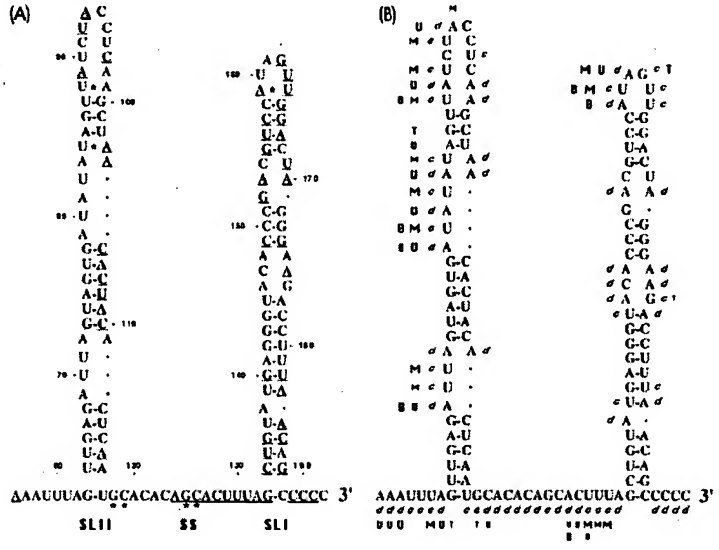
Claims 21-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moss (*Current Biology,* 2002, 12:R138-R140) in view of Yu et al. (*Journal of Virology,* 1999, 73:3638-3648) and Konings et al. (*Journal of Virology,* 1992, 66:632-640)

The claims are drawn to isolated viral nucleic acids comprising 50-131 nucleotides forming a hairpin, wherein 17 to 24 nucleotides bind to a binding site of an mRNA, thereby inhibiting expression of a protein encoded by the mRNA that is transcribed from virus genome, wherein the virus is a DNA virus, RNA virus, or a retrovirus, wherein the hairpin of viral nucleic acids has free energy of folding of at least –11.3 Kcal/mol.

Moss teaches that miRNAs are difficult to find by standard methods for finding genes because they are located in non-coding region and because they are expressed only at specific times or in certain tissues. Moss teaches that "the existence of a fold-back precursor structure was one major criterion in the bioinformatics approach to finding *mir* genes in genomic sequence." See page R139. The hallmark structure of the fold-back miRNA precursor structure is exemplified by the phylogenetically conserved miR-1 precursor RNAs depicted in Figure 1, which is replicated below on page 9 herein. Moss further suggests, "Finding targets of more miRNAs in other systems will certainly give a big boost to the effort to understand their mechanism of action. Some miRNAs may have different mechanisms, and perhaps function like the siRNAs of RNAi. RNAi itself has offered a view into a previously unknown part of the RNA world. Now miRNAs have opened a new vista." See the last 7 lines of page R140. Moss does not teach "viral" miRNA precursors.



Yu et al. teach that conserved RNA motifs comprising up to 100 nucleotides that are located in the 3'-UTR of the Flaviviridae RNA genome. See the secondary structures of stem-loop, hairpin, and bulges, which form fold-back structures located in the 3'-UTR of viral genome depicted in Figure 4, which is replicated below:



Konings et al. teach that optimal and suboptimal free energy foldings of viral RNA hairpin structures can be calculated by using algorithms and computational analysis available in the art. See the entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate viral miRNA precursors by utilizing bioinformatics and algorithms approaches of Moss and Konings et al.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success, because Moss taught that miRNA precursors are located in non-coding region and that "the existence of a fold-back precursor structure was one major criterion in the bioinformatics approach to finding *mir* genes in genomic sequence" and because Yu et al. taught that the fold-back structure located in the 3'-UTR of viral genomic sequence is a conserved motif. As clearly depicted in Figure 1 of Moss and Figure 4 of Yu et al., both miRNA precursor structure of Moss and the viral RNA structure in the non-coding region are characterized by the "fold-back" structure comprising loops, stems, and bulges. One of ordinary skill in the art would have been able to recognize the structural similarities between the miRNA precursor and the viral RNA structure, both of which are located in the non-coding region of the genomic sequences, and based on these similarities, the skilled artisan would have reasonably predicted that viral genomic sequences may have miRNA precursor sequences in the 3'-UTR and therefore would have been motivated to utilize the computational algorithms and bioinformatics tools as taught by Moss and Konings et al. Moreover, since Moss taught that miRNAs might function as siRNAs in the RNAi pathway and suggested that finding more miRNAs in other unexplored organisms would enlighten molecular mechanisms of miRNAs, one of ordinary skill in the art

would have been further motivated to investigate 3'-UTR of viral genomic sequences for the presence of miRNA precursors by virtue of computational algorithms and bioinformatics tools that were technically available in the art at the time the invention was made. Since miRNAs are natural, endogenous inhibitors, one of ordinary skill in the art would have been motivated to use the known computational algorithms to identify potential miRNA precursor sequences in the 3'-UTR of viral genes in an attempt to find molecular therapeutic agents.

Since the technique and skills to achieve the presently claimed invention were within the grasp of a person of ordinary skill in the art at the time the invention was made, it would further have been *prima facie* obvious to perform routine optimization using the computational methods and arrive at the claimed ranges of nucleotide lengths and free energy value. See *In re Aller*, 105 USPQ 233 at 235, which teaches that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and in the instant case, no evidence has been presented that the selection of specific free energy value of –11.3 Kcal/mol and the ranges of nucleotide lengths was other than routine, or that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. In view of the foregoing, the instantly claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Claims 21-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grad et al. (*Molecular Cell*, May 2003, 11:1253-1263) and Lagos-Quintana et al. (*Science,* 2001, 294:853-858) in view of Konings et al. (*Journal of Virology,* 1992, 66:632-640).

The claims are described above.

Grad et al. teach computational and experimental methods of predicting, identifying, and verifying microRNA based on energy, sequence, and structure parameters. They teach that miRNAs have been identified in various species including *Arabidopsis thalinana, C. elegans, Drosophila melanogaster, Mus musculus,* and *Homo sapiens*. They teach that miRNAs are typically 21-24 nucleotides and their precursors are typically 70-90 nucleotides with multiple 1-4 nucleotide bulges and mismatches (page 1254). They teach that computational algorithm approach of predicting and identifying miRNAs overcomes the difficulty of biochemically identifying low-abundant miRNAs (page 1261).

Lagos-Quintana et al. teach methods of isolating miRNAs from *Drosophila melanogaster*. They teach that the isolated miRNAs are also expressed in isolated RNAs from HeLa cells, mouse kidneys, adult zebrafish, *Xenopus laevis*, and *C. elegans*, suggesting that many miRNAs are evolutionarily conserved (pages 853-857). They teach that the isolated and identified miRNAs from *Drosophila melanogaster* and humans are "fairly incomplete and that many more miRNAs remain to be discovered, which will provide the missing evolutionary links." (page 856). They teach that miRNA precursors are about 70 or longer nucleotides in length and comprise sequences that form stem-loop structures of various lengths. See Figures 1, 3, and 4. They also teach that processed miRNAs that bind to target mRNAs are about 21 to 23 nucleotides. See Table 1. They teach that there are methods to detect and identify short,

expressed, functional RNAs such as computer-assisted programs and RNomics (page 857). They teach that "The number of functional RNAs has been widely underestimated and is expected to grow rapidly because of the development of new functional RNA cloning methodologies. The challenge for the future is to define the function and the potential targets of these novel miRNAs by using bioinformatics as well as genetics and to establish a complete catalog of time- and tissue- specific distribution of the already identified and yet to be uncovered miRNAs." See page 857.

The combined references of Grad t al. and Lagos-Quintana et al. do not teach "viral" miRNA precursors, nor do they teach the free energy folding value.

Konings et al. teach that optimal and suboptimal free energy foldings of viral RNA hairpin structures can be calculated by using algorithms and computational analysis available in the art. See the entire reference.

Williams et al. teach that stem-loop structural elements in the 3' UTRs of plus-strand RNA viruses have been reported in the art to function in RNA replication or translation (page 8349). They teach a hairpin structure of 3'-UTR of coronavirus RNA, wherein the hairpin has free energy value of at least –11.3 kcal/mole. See Figure 1C. They teach that the phylogenetically conserved hairpin structure of 3'-UTR of coronavirus RNA functions in viral genome replication (page 8349).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the computational and experimental methods of predicting and isolating miRNAs of Grad et al. to isolate viral miRNA precursors.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because Grad et al. and Lagos-Quintana et al. taught everything contained in claims 24-49 except that the claimed nucleic acid is isolated from a "viral" genome and the hairpin structure of a particular free energy folding value. Although isolated miRNA precursors from a viral genome were not taught in the prior art references, it would have been obvious to one of ordinary skill in the art to explore a viral genome for miRNA precursors because it was known that miRNA precursors are present in a wide array of species and phylum and because computational and experimental methods of predicting, identifying, and verifying microRNAs were available in the art taught by Grad et al. and Lagos-Quintana et al.

See also the Supreme Court decision in *KSR International CO. v. TELEFLEX INC.*, No. 04-1350 (U.S. Apr. 30, 2007). At page 13, the Court stated, "If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." At page 14, the Court stated, "As our precedents make clear, however, the analysis need not seek out precise teachings directed to specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." At page 15, the Court expressed, "The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patent. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way."

In line with the Court's statements, a person of ordinary skill would have implemented algorithms and bioinformatics of Grad et al. and Lagos-Quintana et al. to isolate viral miRNAs with a reasonable expectation of success, because miRNAs were known to be phylogenetically universal throughout various organisms as taught by Grad et al. and Lagos-Quintana et al. Since viral miRNAs were not yet isolated and therefore remained as an unsolved problem in the art, and since the existence of miRNAs in many living organisms was a known fact, and since the desire to unearth more miRANs in different organisms and study their functions was expressed in the art, it would have been obvious for one of ordinary skill in the art to try to isolate viral miRNAs comprising the claimed length parameters at the time the invention was made. Since isolating viral miRNAs was one of the predictable solutions to further explore miRNA functions in different organisms, and since computational methods to analyze optimal or suboptimal free energy foldings of viral hairpin structures was known for more than a decade, a person of ordinary skill in the art would have had a good reason to pursue bioinformatics to isolate viral miRNAs at the time the invention was made. Since the techniques and skills required to make the instantly claimed invention were within, not beyond, one of ordinary skill in the art at the time the invention was made, the instantly claimed invention would have been *prima facie* obvious at the time of filing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-23, 25-26, 29, 31-37, 39-40, 43, and 45-49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,217,807 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention in US 7,217,807 B2 is drawn to an isolated nucleic acid targeted to HIV, which is embraced by the instant claims. Since the

claimed invention in US 7,217,807 B2 is a species of the genus claims of the instant application, the instantly claimed invention is anticipated by, or would have been obvious over, the reference claims.

Claims 21-23, 25-28, 35-37, and 39-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 and 32-36 of copending Application No. 10/707,003. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention in 10/707,003 is drawn to an isolated nucleic acid targeted to human herpesvirus gene, which is fully embraced by the instant claims. Since the claimed invention in 10/707,003 is a species of the genus claims of the instant application, the instantly claimed invention is anticipated by, or would have been obvious over, the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-23, 25-37, and 39-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 12 of copending Application No. 10/605,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are drawn to isolated viral nucleic acids, wherein the viral nucleic acids are transcribed from any viral gene.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner
Art Unit 1635